Message (Digitally Signed)

From: Sharon Lerner [sharon.lerner@theintercept.com]

Sent: 12/22/2021 5:15:12 PM

To: Hamilton, Lindsay [Hamilton.Lindsay@epa.gov]

CC: Daguillard, Robert [Daguillard.Robert@epa.gov]; Carroll, Timothy [Carroll.Timothy@epa.gov]; Dunton, Cheryl

[Dunton.Cheryl@epa.gov]

Subject: Re: Next whistleblower piece

Attachments: signature.asc

Same. Thank you and have a good holiday

Sharon

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PGP:

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On Dec 22, 2021, at 12:07 PM, Hamilton, Lindsay < <u>Hamilton.Lindsay@epa.gov</u>> wrote:

Thanks Sharon, saw it this AM. I appreciate your effort in engaging with us on it!

From: Sharon Lerner < sharon.lerner@theintercept.com >

Sent: Wednesday, December 22, 2021 11:47 AM **To:** Hamilton, Lindsay < Hamilton, Lindsay@epa.gov>

Cc: Daguillard, Robert <Daguillard.Robert@epa.gov>; Carroll, Timothy <Carroll.Timothy@epa.gov>;

Dunton, Cheryl < <u>Dunton.Cheryl@epa.gov</u>> **Subject:** Re: Next whistleblower piece

Thank you, Lindsay. The story is up

https://theintercept.com/2021/12/22/epa-whistleblowers-carcinogen-paint-solvent/

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On Dec 21, 2021, at 5:48 PM, Hamilton, Lindsay <Hamilton.Lindsay@epa.gov> wrote:

Hi Sharon,

A bit more for you here following up on our conversation.

While the PMN substance in question was subject to the polymer exemption, the company still submitted a PMN to the agency. Since the company did submit the PMN, EPA conducted the risk assessment and did not identify any hazards or risks associated with the PMN substance and issued a "not likely" determination.

Companies do not have to use the polymer exemption, and at times a company will choose to submit a PMN for business/other reasons (even if they qualify under the exemption). For example, some companies have conveyed to EPA that they cannot get their customer to use their product until it is on the TSCA Inventory. In order to get on the Inventory, a company must go through the PMN process and EPA will conduct a full risk assessment.

Thanks, Lindsay

From: Sharon Lerner < <u>sharon.lerner@theintercept.com</u>>

Sent: Tuesday, December 21, 2021 10:10 AM **To:** Hamilton, Lindsay < Hamilton.Lindsay@epa.gov>

Cc: Daguillard, Robert < <u>Daguillard.Robert@epa.gov</u>>; Carroll, Timothy < Carroll.Timothy@epa.gov>; Dunton, Cheryl < Dunton.Cheryl@epa.gov>

Subject: Re: Next whistleblower piece

Hi Lindsay-

I just wanted to follow up because, upon reading your response, I fear that I didn't make it clear that I already discuss the memo you attached in the story. In fact I link to it. And I note that the majority of scientists who were discussing the issue of PCBTF in the paint assessment did NOT agree with the interpretation you give of the memo - that it meant that it was subject to the polymer exemption. To be clear, that was the central dispute, the whistleblowers (3 in this case) and several other EPA staff members who were involved in the discussions — and whose emails I've reviewed — did not believe that the memo made it clear that the dangers of PCBTF should not be included in the assessment. Instead, they had a variety of interpretations of the memo, including that 1) the dangers of PCBTF should be included in the assessment, 2) PCBTF should be sent to the existing chemicals for assessment, 3) if NCD did not include the risks in the assessment, other actions should be taken.

One whistleblower said: "There's a final paragraph stating that if there is nothing done, if we're not going to do the review ourselves, at a bare minimum, the risk managers should be communicating what we found to the chemical company so that they know that they have to take some sort of action."

I'm just sending this in case you want to clarify your response at all. Thanks, Sharon Sharon Lerner
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On Dec 20, 2021, at 8:26 PM, Hamilton, Lindsay Hamilton.Lindsay@epa.gov> wrote:

Hi Sharon,

Here is a response for you. Thanks so much.

EPA and the Office of Chemical Safety and Pollution Prevention are committed to the agency's mission to protect human health and the environment.

Regarding the specific PMN in question:

The PMN substance that is the question of this inquiry is a polymer contained in a paint. The PMN substance is a polymer and it qualifies for the <u>polymer exemption</u>.

As background, the 1985 memo, attached, describes how to address a circumstance in which an existing chemical is included as an intentional component of a PMN substance and when that existing chemical poses risk. Under the referenced policy, the solvent would be referred to the Existing Chemical Program and would not be addressed under the new chemical review because the solvent in question is not intentionally part of the PMN substance. The relevant language from the memo that describes this exemption is found on page 9, item #1. The 1985 memo, while written in the context of TSCA as it existed in 1985, contains guidance that remains useful in reviewing new chemicals under the amended law.

When Congress wrote TSCA in 1976 it exempted every chemical in commerce from having to go through the new chemicals assessment process. The 2016 amendments to TSCA direct EPA to do risk evaluations on the existing chemicals that were grandfathered in under the original law and requires EPA to have at least 20 risk evaluations in process at any given time. EPA is meeting those requirements. While one can accurately state that many of the chemicals that were grandfathered into the 1976 law may pose risks and remain unrestricted under TSCA, the PMN substance subject to this inquiry was not handled inappropriately or inconsistently with TSCA.

Regarding scientific integrity:

Restoring scientific integrity has been a top priority across the Agency since the beginning of the Biden-Harris Administration. Significant efforts are underway to understand and address concerns that have been raised. We are continuing to make improvements to the program and are cooperating fully with the ongoing IG investigation.

EPA's new chemicals program has been engaging in targeted, all-handson deck efforts to catalogue, prioritize and improve its procedures,
recordkeeping and decision-making practices related to review and
management of new chemicals under TSCA. The new chemicals
program has already implemented several important changes to provide
additional opportunities for resolution of differing scientific opinions,
and to allow input into the decision-making by EPA subject matter
experts outside of the division. This includes, for example, a revised
process for review and finalization of human health risk assessments,
and the formation of a new advisory body within the program to review
and consider both scientific and science policy issues related to new
chemical submissions.

The following are examples of additional actions OCSPP has already taken to address scientific integrity concerns across the office:

- Ongoing cooperation with Inspector General's investigation;
- Implementation of several new processes for scientists to elevate their concerns and get a review wherever there's disagreement;
- A change in the performance metric for the New Chemicals Division, such that expediency of reviews is not the only measure of success, see FY 2022-2026<u>strategic plan draft</u>;
- Series of scientific integrity trainings for the entire office to emphasize the importance of these policies;
- Independent contractor review of the TSCA New Chemicals program to capture feedback from employees and management about any potential workplace barriers and opportunities for organizational improvement; and
- Ongoing collaboration with EPA's Office of Research and Development on furthering scientific research relevant to new chemical reviews.

Responses to your specific questions:

QUESTION: IS THIS ACCURATE, THAT MANUFACTURERS "ALMOST ALWAYS" SUBMIT THE INFORMATION ABOUT THEIR PRODUCTS IN PMNS AS CBI? OR IS IT ALWAYS THE CASE? OR JUST SOMETIMES?]

EPA often receives CBI claims associated with various information within PMNs, and the specific claims (i.e., types of information claimed as CBI) will vary case to case.

[QUESTION: WHEN ARE THOSE 20 ASSESSMENTS EXPECTED TO BE FINALIZED?]

The policy changes associated with TSCA risk evaluations that were announced on June 30 will be carried through to all future risk evaluations, including the next 20 and ongoing manufacturer requested risk evaluations. The Agency is reviewing the next 20 chemicals to determine the extent of the effect of policy changes on the scopes of the risk evaluations. Upon completion of this review, EPA intends to provide updates regarding any changes. Generally, these risk evaluations represent a multi-year effort that, under TSCA, can take up to 3.5 years from the designation as a high-priority chemical to complete.

[QUESTION: IS THERE ANY UPDATE ON THIS? ARE THE 8ES AVAILABLE YET IN CHEMVIEW?]

Due to overarching (staff and contractor) resource limitations, the agency was not able to continue the regular publication of 8(e) submissions in ChemView, a heavily manual process, after 1/1/2019. EPA has continued to take in and review 8e submissions; however, a single staff person was dedicated to processing the submissions for posting to ChemView. That staff person retired in December 2018. Other staff within the unit that would historically also do this type of work were fully occupied conducting other work to increase transparency associated with TSCA new chemicals submissions in response to a commitment made by the past EPA Administrator to Senator Carper. See: https://insideepa.com/daily-news/win-dunns-confirmation-epa-vows-revise-key-tsca-programs.

The TSCA program has been and remains incredibly underfunded. The previous Administration never asked Congress for the necessary resources to reflect the agency's new responsibilities under amended TSCA. The Biden-Harris Administration has asked for significantly more resources for this program in the 2022 budget request to ensure we're meeting our obligations under TSCA, most importantly protecting human health and the environment.

In the future, as resources allow, EPA will continue to strive to make TSCA 8(e) reports publicly available in ChemView in the interest of increased transparency. In the meantime, in 2021 EPA reinstated contractor funding to ensure all TSCA 8(e) reports receive initial screening and any serious health and safety risks are flagged for further review. EPA is also currently transforming the 8(e) publication process to be more automated and to the extent that resources allow, will resume making these submission types publicly available in ChemView again soon.

Thanks, Lindsay From: Sharon Lerner <sharon.lerner@theintercept.com>

Sent: Monday, December 20, 2021 11:37 AM

To: Daguillard, Robert < Daguillard.Robert@epa.gov>

Cc: Carroll, Timothy < Carroll. Timothy@epa.gov >; Hamilton, Lindsay

< Hamilton.Lindsay@epa.gov>; Dunton, Cheryl

<Dunton.Cheryl@epa.gov>

Subject: Re: Next whistleblower piece

Yes confirming that we can update at any point after publication.

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On Dec 20, 2021, at 11:35 AM, Sharon Lerner <sharon.lerner@theintercept.com> wrote:

We can update at any point, I believe. I put in a note to my editor to confirm, will let you know as soon as he gets back to me.

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PGP:

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On Dec 20, 2021, at 11:27 AM,
Daguillard, Robert
Nobert@epa.gov wrote:

Thanks, Sharon. Duly noted. How late can you update your story?

From: Sharon Lerner

<sharon.lerner@theintercept.com>
Sent: Monday, December 20, 2021

11:24 AM

To: Daguillard, Robert

<<u>Daguillard.Robert@epa.gov</u>>
Cc: Carroll, Timothy
<<u>Carroll.Timothy@epa.gov</u>>; Hamilton,
Lindsay <<u>Hamilton.Lindsay@epa.gov</u>>

Subject: Re: Next whistleblower piece

Robert-

This is going to come out tomorrow. So sorry for the shorter than usual turnaround time

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On Dec 20, 2021, at 9:08 AM, Daguillard, Robert <<u>Daguillard.Robert@ep</u> <u>a.gov</u>> wrote:

Sorry, Sharon: I'm sure you realize this week will see lighter-than-usual staffing: We're closed Friday, to say nothing of staff going on leave beforehand. Are you planning to put this piece out any time before, say, the first of the year? How urgently do you need it?

Thanks as always, R.

From: Daguillard, Robert <<u>Daguillard.Robert@ep</u> <u>a.gov</u>> Sent: Monday, December 20, 2021 9:04 AM

To: Sharon Lerner sharon.lerner@theint

ercept.com>

Cc: Carroll, Timothy
<Carroll.Timothy@epa.
gov>; Hamilton, Lindsay
<Hamilton.Lindsay@ep
a.gov>; EPA Press Office
<Press@epa.gov>
Subject: RE: Next

Good morning Sharon,

whistleblower piece

I know your message is addressed to Tim and Lindsay, but I wanted to acknowledge on their behalf.

Best as always, R.

From: Sharon Lerner <<u>sharon.lerner@theint</u> ercept.com>

Sent: Monday, December 20, 2021 8:53 AM

To: EPA Press Office <<u>Press@epa.gov</u>> Cc: Carroll, Timothy <<u>Carroll.Timothy@epa.gov</u>>; Hamilton, Lindsay <<u>Hamilton.Lindsay@ep</u>

a.gov>

Subject: Re: Next whistleblower piece

Hi Tim and Lindsay-Just circling back on this to make sure you received it. Thanks, Sharon

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> On Dec 17, 2021, at 10:19 AM, Sharon Lerner <sharo n.lerner

<u>@thein</u> tercept.

<u>com</u>> wrote:

Hi Tim and the press office-

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EPA whistle blowers

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Thank

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Sharon

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In this piece, I write about the assess ment of a paint product that was finalize d on Decem ber 19, 2019. The paint contain ed the solvent parach lorobe nzotrifl uoride, or **PCBTF** , which made up half of the produc t by weight. **PCBTF** presen ts numer ous health hazard s, accordi ng to a <u>2009</u> <u>report</u> from the Nation al

Toxicol ogy

Progra m. Earlier in 2019, Califor nia had listed **PCBTF** under **Propos** ition 65, basing its dec ision o n eviden ce that the chemic al had caused liver tumors in both male and female mice. And just month before the produc t was being assesse d by EPA's NCD, the Intern ational Agency for Cancer Resear ch had <u>de</u> <u>emed</u> **PCBTF**

a likely human carcino gen.

The toxicol ogist who was assigne d the case of the paint noted that it contai ned **PCBTF** and en gaged in conver sations - in person and over email about how to handle it. While numer ous assesso rs agreed that the risks of **PCBTF** should be include d in the assess ment of the new paint, one off icial, who holds a

senior

leaders hip role in the agency , said she felt that the danger s of **PCBTF** should not be mentio ned in the assess ment. In a Decem ber 18 email, she describ ed the chemic al as "just a solvent there as a part of makin g it." She argued that, b ecause it didn't appear that **PCBTF** was meant to be an ingredi ent in the final produc t, its health effects should

not be consid ered in the assess ment.

ment. The official , whom the whi stleblo wers asked me not to name in the piece, also pointe d the assesso rs to a 1985 memo, which addres sed when **EPA** should assess the risk from a new chemic al substa nce. The whistle blower describ e her as angrily throwi ng the memo at them

and said that tensio ns with this official over identif ying chemic als' risks were runnin g high.

g high. The official saw the memo as eviden ce that **PCBTF** should n't be consid ered when assessi ng the paint and told the toxicol ogists assem bled at the meetin g to "Read it. Follow it." But several of the assesso rs interpr eted the memo differe ntly, pointin

g out

that some section seeme d to suppor t the inclusi on of **PCBTF** in the assess ment and noting that others laid out the possibi lity of referri ng the compo und to the Existin g Chemi cals progra m for assess ment. The memo also laid out other actions to be taken if the new chemic als divisio n did not assess the produc t. "There'

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final paragr aph stating that if there is nothin g done, if we're not going to do the review ourselv es, at a bare minim um, the risk manag ers should be comm unicati ng what we found to the chemic al compa ny so that they know that they have to take some sort of action, " one of five agency scienti sts whoex presse d their suppor t for includi

ng the danger s of **PCBTF** in the assess ment of the new paint said. This did not happe n, accordi ng to the whistle blower s. "It does seem that we need to be concer ned about the risk of the new chemic al plus existin g chemic als that pose risk," anothe r of the toxicol ogists wrote. "I think the human health assesso rs need to feel comfor table

that we are doing our best to protect public health.

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ment of the paint. I n a version of the docum ent entere d into the divisio n's compu ter system on Decem ber 17, the toxicol ogist had noted that **PCBTF** can be absorb ed throug h the lungs, GI tract, and skin. He also identifi ed cancer as one of its hazard s, along with liver, kidney, lung, and adrena l gland effects, and calcula ted the

cancer risk associa ted with precise amoun ts of the paint. But the next day, hours after the conten tious meetin g at which the memo was discuss ed, the official who had argued against the inclusi on of the inform ation inserte da note into the assess ment, asking him to delete all referen ces to **PCBTF** The toxicol ogist

did not delete

the inform ation, but the official who had led the charge against makin g any mentio n of the risks of **PCBTF** did. On Decem ber 18, she posted an update d version of the assess ment that crosse d out the list of PCBT's effects and the exposu re levels above which it could be expect ed to cause cancer. In its place, she inserte d a

new

senten ce: "For the new chemic al substa nce (polym er), **EPA** did not identif y a hazard ." The next day, she signed off on the docum ent she had change d, publicl y declari ng that the agency had found that it did not pose a hazard The whistle blower s said that the remov al of the scientif ically accurat warnin g left

the

scienti sts who do chemic al assess ments feeling powerl ess to do their jobs and win an argum ent within their workpl ace on its merits. "You'v e got multipl e people saying, hey, this deserv es more careful consid eration . But she made a call, overro de everyb ody, shut it down, and we never talked about it again," said one. The

whistle

blower said that **EPA** could have taken several possibl e actions to alert the public about the paint. "But the conver sation is not 'what can we do within these limitati ons?" he said. "Instea d their questio n is, how little can we get away with? What can we get off our plate?' Не also said that "When new

inform ation comes in that

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shows that someth ing is less toxic than what we though t, that gets used right away. But if it shows that there are new concer ns that we weren't aware of before, sudden ly the level of scrutin y goes way up." I asked David Michael s, the former head of OSHA, about this case, which involve s the potenti al exposur e to worker

s. And he said "T he EPA is suppos ed to be consid ering whethe worker s' exposu res could be toxic. This is a failure of EPA to follow the law." I note in the story that the whistle blower s are not allowe d to disclos e the produc ts name or anythi ng else about it becaus e, as is almost always the case, the manuf acturer S

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face penalti es if they disclos ed them and that they can identif y PCBTF withou penalt becaus e, as an existin g chemic al, it is not subject to the same restrict ions. I note that the paint is not the only produc t that contai ns **PCBTF** and that none of 7 safety data sheets I found for produc ts that contai n it identifi ed the risk of

cancer. I also note that there are many chemic als for which the **EPA** has failed to update regulat ion based on the most recent science "We never go back and review these cases and put on new restrict ions for their use," said one of the whistle blower s. I note that the **EPA** chose 20 <u>"hig</u> <u>h</u> priorit y" subs

tances to be

evaluat ed under the update d chemic als law in 2019. [QUES TION: WHEN ARE THOS E 20 ASSES **SMEN** TS **EXPEC** TED TO BE FINAL IZED?]

I also note that th ere is no clear way to ensure that the agency update s its assess ments - or even inform S anyone when it learns about the harms of a chemic al and refer back to

my rece nt story <u>on</u> <u>8e sub</u> <u>mission</u>

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PGP: CB29 D9FF 9285 3205 087E 83 A1 0C30 2F39 4F30 8BFE <Risks of existing chemicals in PMNs (002).pdf>